Guidance for Industry and
the Clinical Community

# MDR Reporting Guidance For Date-Related Problems Including Y2K

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**U.S. Department of Health and Human Services**
**Food and Drug Administration**
**Center for Devices and Radiological Health**

**Reporting Systems Monitoring Branch**
**Division of Surveillance Systems**
**Office of Surveillance and Biometrics**

# Preface

## Public Comment

Comments and suggestions may be submitted at any time for Agency consideration, to Susan E. Bounds, HFZ-533, 1350 Piccard Drive, Rockville, Maryland 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance, contact Victoria Schmid at 301-594-2735 or by electronic mail at VAS@CDRH.FDA.GOV

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This guidance document represents the agency's current thinking on reporting of date-related medical device problems. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance may be used by the medical device industry and medical device user facility community to determine when and how to report medical device events that are computer-related problems associated with the Year 2000 (Y2K) or other date-related problems.

Many medical devices contain computer circuits and software that incorporate two digits to represent the year. This use of two digits is expected to present a problem for some of the devices that remain unmodified when the year 2000 arrives. The performance of the devices may be affected in unexpected and unpredictable ways when the date changes from December 31, 1999 to January 1, 2000. Date-related software problems may also exist for other critical dates, such as February 29, 2000, or September 9, 1999. The reportability issues discussed in this document apply to other critical dates as well as the "Y2K" problem.

There is the potential for many medical devices containing computer circuits and software to be affected by the two digit year. Medical device manufacturers are aware of this Y2K problem and most have taken steps either to modify their devices or to develop workaround procedures, so that their devices will continue to function properly now and into the new millennium.

A product that uses only two digits to indicate the year in displays or printed records may meet FDA's definition of Year 2000 Compliant, provided the displayed year is correct before and after January 1, 2000. A product that uses only two digits to represent the year in internal device operations or in external data communication may also be compliant, provided the use of a two digit year does not result in incorrect functioning of the device. Examples of Y2K noncompliance include: incorrect sorting or storage of information and the transmission of data which is incorrect or ambiguous when compared to the design specifications of the product and its data interface specifications. The definition for a product that is Year 2000 Compliant is on FDA's Web site at:

http://www.fda.gov/cdrh/yr2000/y2kintro.html .

## I. Manufacturers:

A. Device Failure Which Results in Death or Serious Injury:

The Medical Device Reporting (MDR) regulation [21 CFR 803.50] requires a manufacturer to submit a report when it becomes aware of information that reasonably suggests that its device may have caused or contributed to a death or serious injury. The event is required to be reported whether or not the event was a result of a Y2K failure.

B. Reportable Device Malfunction:

The MDR regulation [21 CFR 803.50] requires each manufacturer to report when it becomes aware of information that reasonably suggests that its device has malfunctioned and would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. A malfunction that would be likely to cause or contribute to a death or serious injury must be reported regardless of whether or not the event was a result of a Y2K failure.

C. Device Malfunction That Is Not Reportable:

A malfunction that is not likely to cause or contribute to a death or serious injury is not reportable. Examples of events of this type include the following:

- Failure to change to the year 2000 which is part of a record-keeping function (a date displayed for recording a test result) and not likely to result in an adverse event.

- The device performs as intended but displays an error message, such as "set clock", and there is no likelihood of it adversely affecting the patient.

## II. User Facilities:

A user facility is required by the MDR regulation [21 CFR 803.30] to submit a report when it becomes aware of information that reasonably suggests that a device has or may have caused or contributed to a serious injury or the death of a patient at the facility. An event that meets this criteria is reportable regardless of whether or not the event resulted from a Y2K failure.

A report of a device-related death is reported to both FDA and the manufacturer while a device-related serious injury is reported only to the manufacturer. The address for mandatory reports to FDA is: FDA/CDRH, FDA User Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

A user facility conducting medical device testing to try to uncover Y2K problems may obtain results that contradict manufacturer Y2K compliance statements. User facilities are encouraged to report this information to the manufacturer and FDA. A voluntary report to the FDA MedWatch office may be faxed to 1-800-FDA-0178 or mailed to MedWatch, The FDA Medical Products Reporting Programs, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787.

## III. Importers:

Importer reporting requirements are currently covered by the Distributor MDR regulation [21 CFR 804]. An importer reports when it becomes aware of information that reasonably suggests that one of its devices may have caused or contributed to a death or serious injury. An importer also reports when it becomes aware of information that reasonably suggests that one of its devices has malfunctioned and is likely to cause or contribute to a death or serious injury if the malfunction were to recur. An event that meets either criterion is reportable by an importer whether or not the event resulted from a Y2K failure.

## IV. Exemptions Available for Recurring Date Events:

A. An MDR reportable event, other than a death report, that is associated with a remedial action is eligible for exemption from being reported under the Remedial Action Exemption (RAE) E19960001 issued July 30, 1996. A remedial action is defined within the MDR regulation [21 CFR 803.3(y)] as an action other than routine maintenance or servicing of a device where such action is necessary to prevent recurrence of a reportable event.

   To qualify for this exemption, a firm must provide FDA with the appropriate notifications and must comply with the other conditions identified in the RAE document, a copy of which is available on FDA's Web site at:

   http://www.fda.gov/cdrh/manual/remedial.html .

   A firm that initiates a remedial action that the FDA classifies a Class I recall is not authorized to use this exemption. A firm that begins to report under the RAE will be required to suspend its use and resume filing individual reports should it become aware that FDA has classified its remedial action a Class I recall.

B. A manufacturer or importer may also receive numerous reports of MDR reportable malfunctions that are associated with Y2K problems where the firm decides not to initiate a remedial action. FDA intends to develop a separate exemption, in accordance with 21 CFR 803.19, to cover Y2K events where no remedial action is taken to correct the malfunction.

   This new exemption will permit a firm to submit a single individual MDR report for the malfunction. A death or serious injury associated with the identical malfunction, however, will still be reported individually.

## V. Coding:

FDA has established specific codes to report Y2K problems, as well as other date aberrations. Accordingly, the following codes should be used in addition to other appropriate codes in blocks F10 and H6 of the FDA form 3500A (MedWatch form).

Device Problem Codes:

2581 – Year 2000-related problem
2582 – Date-related problem, not Y2K

Conclusion Codes:

90 – Year 2000-related problem
91 – Date-related problem, not Y2K